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EXAMINER	
HIGGINS, GERARD T	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
10/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,593	MOMMA ET AL.	
	Examiner	Art Unit	
	GERARD T. HIGGINS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,11,12 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,11,12 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/15/2009 has been entered.

Response to Amendment

2. The amendment filed 09/15/2009 has been entered. Currently claims 1-6, 9, 11, 12, and 20 are pending and claims 7, 8, 10, and 13-19 are cancelled.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **24** see [0023]. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be

labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 2 and 20 are objected to because of the following informalities: the limitation "together forming a core filled wire" is objected to grammatically because it is unclear to what limitations "together" is referring. This objection will be removed if the limitation is changed to "together the comparatively radiopaque material and the cover layer form a core filled wire." Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6, 9, 11, 12, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 2 and 20, the Examiner does not find support for the limitation "including legs ***defining*** apertures" in the specification as originally filed. The Examiner does find support to claim that the legs define the mesh [0019] in that the legs **12** form support portions **14** which define the mesh **18**; however, the mesh is not necessarily the same as the apertures [0022]. An aperture results from cutting out a leg **12** or a connecting leg **16**. This rejection will be withdrawn if the limitations are changed to "including legs and apertures, wherein the apertures are produced by cutting out legs, and having at least one marker element welded in at least one of the apertures."

With further regard to claims 2 and 20, the Examiner does not find support to claim that the marker element is "welded to at least one leg and disposed in at least one of the apertures" in the specification as originally filed. In all instances of welding the marker elements into the apertures, the marker element is welded at two places. Applicants appear to be mixing the embodiment of Figure 1 and the embodiment of Figure 4. The embodiment of Figure 1 possesses apertures, while the embodiment of Figure 4 does not. This rejection can be overcome by deleting the limitations "to at least one leg and disposed" from the claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

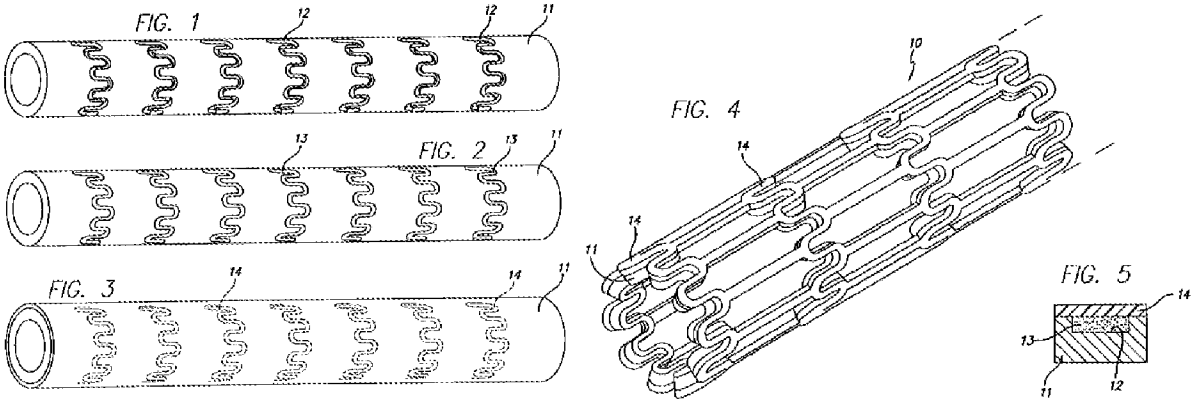
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6, 9, 11, 12, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dang (6,471,721).

The Examiner again notes the presence of product-by-process limitations in applicants' claims. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The Examiner notes that any article that has the resultant structural limitations despite being formed by a different process will be held to anticipate the claimed article. The limitation regarding the fact that the carrier structure comprises "a cut out metal tube" is a product-by-process limitation. The fact that the apertures have "at least one marker element welded to at least one leg and disposed in at least one of the apertures" is a product-by-process limitation in that the resultant article could have all of the apertures filled in with marker elements, and therefore there would not be any apertures in the finished article. The fact that the comparatively radiopaque material is "filling and completely enclosed by a cover layer" implies that a hollow wire was filled with material; however, if an article is found that comprises a core of comparatively radiopaque material and a cover layer of a metal or metal compound other than the comparatively radiopaque material it will be held to anticipate the claim.

With regard to claim 2, Dang discloses the device of Figures 1-5.



The stent **10**, which reads on applicants' carrier structure, comprises a radiolucent material, i.e. "difficult to visualize fluoroscopically" (col. 3, lines 22-31 and col. 5, lines 12-23). The stent is produced from a cut out metal tube stock **11** (see Figure 1). The device may have radiopaque material **13**, which reads on applicants' comparatively radiopaque material, incorporated therein (col. 5, lines 38-41). Please note from Figures 1-3 that the radiopaque material is incorporated in cylindrical cut grooves **12** around the circumference of the tube stock (Figure 1-3). The cylindrically cut grooves are then covered over with the sputtered coating **14**. The tube stock **11**, with the cylindrically cut grooves **12**, filled with radiopaque material **13**, and then covered over with the sputtered coating **14** read on applicants' at least one marker element or core filled wire. The marker elements are attached to the rest of the carrier structure **10** (Figure 4). Please note that the marker elements are integral to the carrier structure; however, the longitudinal sections of the stent **10** spanning the distance between the cylindrical marker elements are apart of and also read on applicants' carrier structure (Figure 4). The radiopaque material **13** is completely enclosed by the tube stock **11** and

the sputtered coating **14**, which together (**14** and **11**) read on applicants' cover layer. The material for the tube stock and the sputtered coating include metals and metal alloys (col. 5, lines 14-20 and col. 6, lines 9-11).

Although formed by a different process, i.e. forming grooves **12**, filling with radiopaque material **13** and covering over with the sputtered coating **14**, the Examiner deems the cover layer (**14** and **11**) has the same resultant structure as a hollow wire into which the radiopaque material fills the core thereof as claimed. Additionally, although the marker elements are integral to the carrier structure and not "welded to at least one leg and disposed in at least one of the apertures" as claimed, the Examiner deems the resultant structure to be the same, and therefore the device of Dang continues to anticipate the claimed invention as well as the requirement that the "legs define apertures."

With regard to claim 1, considering the disclosure at col. 5, lines 14-20 and col. 6, lines 9-11, the Examiner deems that Dang disclose forming both the tube stock **11** and the sputtered coating **14** from nitinol, which is a titanium-nickel alloy. The Examiner provides as a basis for this finding the disclosure at col. 6, lines 9-11, which talks about the sputtered coating **14**, and states "[w]hile one preferred material for the sputtering is 316L stainless steel, other suitable material can be also used." The disclosure at col. 5, lines 14-20 states that the preferred material for the tube stock **11** "is 316L stainless steel, although other materials such as…nitinol…can be used." The Examiner deems that the "other suitable material" mentioned for the sputtering **14** includes all the alternative materials mentioned for the tube stock **11**, including nitinol.

With regard to claims 3 and 11, the device may be comprised of nitinol, which is a nickel-titanium alloy (col. 3, lines 22-30). The device can be self-expanding as taught by Dang at col. 1, lines 24-26, where they state that the stent may be deployed "automatically by the removal of a restraint."

With regard to claim 6, the Examiner has discussed with regard to claim 2 how the tube stock **11** and the sputtered coating **14**, which together (**14** and **11**) read on applicants' cover layer, and that longitudinal sections of the stent **10** spanning the distance between the cylindrical marker elements are apart of and also read on applicants' carrier structure. The marker element and the carrier structure are formed from the same materials, i.e. parts **14** and **11**. Also the marker elements are clearly attached to the carrier structure by way of parts **14** and **11** and therefore the stent of Dang meets the limitation that the "marker element is attached to the carrier structure at the cover layer."

With regard to claim 9, the radiopaque material is incorporated as the cylindrical marker elements as seen in Figures 1-4. It is clear from the Figures that the cylindrical marker elements at the two longitudinal ends of the stent **10** are attached to the carrier structure in a region of a longitudinal end of the stent.

With regard to claim 12, Dang discloses at col. 5, lines 41-44 that the radiopaque material may be gold or platinum.

With regard to claim 20, the Examiner has discussed the structure of the stent with regard to claim 2 above. The stent of Dang is designed to be placed into a patient

as that is what stents are designed to do; furthermore, Dang discloses at col. 1, lines 14-27 that stents are particularly adapted to be implanted into a patient's body.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,471,721) as applied to claim 3, in view of applicants' own admissions.

Dang discloses device that may be comprised of nitinol, which is a nickel-titanium alloy (col. 3, lines 22-30) that is inherently a shape memory metal; however, he does not disclose a device that has a design that may allow for temperature dependent change in the configuration of the stent.

Applicants state that it is known to one of ordinary skill in the art to build stents of certain design that allow for temperature dependent change in the configuration of the stent [0026].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to build a stent of a certain design in order to take advantage of this known temperature dependent change in the configuration of the stent. The results would have been predictable; further, the motivation to use this design would be to

remove the need for a restraint mechanism or a balloon to expand the stent. This would lead to a product that was cheaper and much more easily deployed.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,471,721) as applied to claim 2, in view of Kranz et al. (6,312,456).

With regard to claim 5, Dang discloses all of the limitations of applicants' claim 2 in section 8 above, and it also discloses at col. 6, lines 56-57 that a biocompatibility layer may be added; however, it fails to disclose that the biocompatibility layer contains silicon carbide.

Kranz et al. disclose at col. 2, lines 51-54 that silicon carbide is used as an outer coating layer on the biocompatible stent and counteracts thrombosis formation; further, at col. 4, lines 27-30 that the silicon carbide is used as an outer covering to avoid stenosis.

Since Dang and Kranz et al. are both drawn to stents, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the silicon carbide outer covering layer of Kranz et al. as the biocompatibility layer of Dang. The motivation for doing so has been stated above and includes *inter alia* counteracting thrombosis formation; further, the overcoating of silicon carbide on the device of Dang would produce a stent that had a multilayered covering layer, and as such would still include the nitinol cover (a metal or metal compound) as well as the additional layer of silicon carbide.

Response to Arguments

12. Applicant's arguments, see Remarks, filed 09/15/2009, the rejection of the term "and forming a hollow wire" under 35 U.S.C. 112, first paragraph and the rejection of claims 1-6, 9, 11, 12, and 20 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The relevant rejections have been withdrawn.

13. Applicant's arguments filed 09/15/2009 have been fully considered but they are not persuasive.

Applicants argue that welding is a unique uniting process in metallurgy that leaves a discernible bond, and therefore the method of making applicants' product renders it different from the prior art stent.

Applicants are reminded that "the arguments of counsel cannot take the place of evidence in the record", *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). It is the examiner's position that the arguments provided by the applicant regarding Dang must be supported by a declaration or affidavit. As set forth in MPEP 716.02(g), "the reason for requiring evidence in a declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 24 and 18 U.S.C. 1001". The Examiner has deemed that resultant article of Dang possesses all of the structural limitations of applicants' product-by-process claims. Applicants have not presented any evidence to show that their

resultant article will be structurally different, and therefore applicants have not overcome the Examiner's *prima facie* case.

Applicants argue on page 6 of their Remarks that the Examiner has not cited a piece of art that has a resultant article with all of the apertures filled.

The Examiner respectfully disagrees and notes that the entire cylindrical end section of Dang is comprised of marker element. This is the same as applicants' description of a possible embodiment at [0023], where the entire end section is comprised of an X-ray marker element. The lack of the end portion **20** as defined by applicants' specification would read on an "aperture" as claimed. These end portions are welded onto the outermost connecting legs **24** of applicants', which is the marker element disposed in at least one aperture as claimed. Turning to Dang, the Examiner notes that the entire cylindrical end section of Dang is comprised of marker element; furthermore, the cylindrical end section is integral to the carrier structure and connected to the longitudinal sections of the stent **10** spanning the distance between the cylindrical marker elements. This continues to read on applicants' product-by-process limitations that the marker element is "welded to at least one leg and disposed in at least one aperture" as claimed.

Applicants argue on page 7 of their Remarks that Figure 3 of the current specification and Figure 5 are "clearly differentiable" and that the cover layer of Dang does not form a core filled wire with the comparatively radiopaque material.

Again the Examiner notes that the comparatively radiopaque material "filling" a cover layer to form a "core filled wire" is a product-by-process limitation. The Examiner

again respectfully disagrees with applicants' arguments and notes that Figure 3 of the current invention and Figure 5 of Dang are not "clearly differentiable" as suggested. Applicants' attention is drawn to their Figure 3 and Figure 5 of Dang.

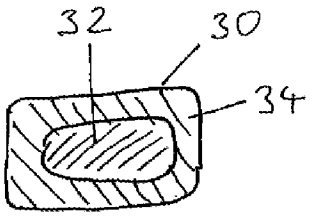
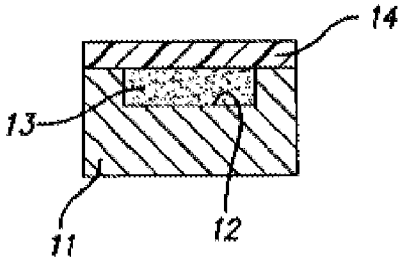


Fig. 3

FIG. 5



The Examiner argued in the previous Office action mailed 10/29/2008 and has restated in this rejection that the tube stock **11** and the sputtered coating **14** *combined* read on applicants' cover layer **34**. The Examiner maintains that although the cover layer of Dang is formed by a different process, i.e. forming grooves **12**, filling with radiopaque material **13** and covering over with the sputtered coating **14**, the Examiner deems the cover layer (**14** and **11**) has the same resultant structure as a hollow wire into which the radiopaque material fills the core thereof as claimed. Although the tube stock **11** and the sputtered coating **14** are shown to be distinct materials in Figure 5 of Dang, when the coating **14** of Dang is sputtered it will form a single material with the tube stock **11** as the two elements are comprised of the same material. This Examiner deems that this reads on applicants' "core filled wire," and applicants' arguments have not overcome this *prima facie* case.

Applicants argue on page 8 of their Remarks that the longitudinal sections of Dang, without the cylindrical marker elements, would not read on applicants' carrier element and would not define apertures as claimed.

The Examiner disagrees and notes first that the marker elements of Dang are integral to their carrier structure as taught above. The Examiner specifically set forth that the stent **10** reads on applicants' carrier structure (see section 8); however, the longitudinal sections spanning the distance between cylindrical marker elements are apart of, and also read on, applicants' carrier structure.

With regard to the apertures argument, the Examiner notes that applicants point out on page 6 of their Remarks that "the claims do not recite apertures in the finished article." The Examiner agrees with this statement and notes the broadest reasonable definition of the word "defining" as set forth by Merriam-Webster Online: "**2a**: to fix or mark the limits of." The longitudinal section of Dang would read on applicants' legs defining apertures" as claimed because they would define the region wherein the cylindrically shaped marker elements are to be inserted; however, the Examiner again reminds applicants' that these are product-by-process limitations as there are no apertures in the finished product, as stated by applicants. The Examiner deems that the stent of Dang, although formed by a different process, anticipates applicants' "legs defining apertures and having at least one marker element welded to at least one leg and disposed in at least one of the apertures" as claimed. The Examiner has set forth his *prima facie* case and applicants have not overcome this case.

With regard to the rejection of claims 4 and 5 using applicants' own admissions and Kranz et al., the Examiner notes that applicants' own admissions and Kranz et al. are teaching references used to meet the limitations of the individual claims. The Examiner maintains that Dang anticipates all of the limitations of applicants' claims 2 and 3.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERARD T. HIGGINS whose telephone number is (571)270-3467. The examiner can normally be reached on M-Th 10am-8pm est. (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Ruthkosky can be reached on 571-272-1291. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Ruthkosky/
Supervisory Patent Examiner, Art Unit 1794

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